#### REMARKS

This amendment is responsive to the Office Action dated December 28, 2007. Claims 1-31 are pending. Claims 1, 8-10, 16-24, 30 and 31 are amended herein.

Applicant traverses all rejections of claims in this application, and requests reconsideration in view of the arguments below.

### Amendments for Antecedent Basis

Claims 17-22 have been amended to change "care provider" to "user", for proper antecedent basis.

# § 102 Rejections of the Claims

Claims 1-3, 7-8, 15-19, 21, 24, and 27-31 have been rejected under 35 U.S.C. § 102 as being anticipated by Kramer, U.S. Patent No. 5,405,362.

Independent claim 1 has been amended to clarify that the method includes the steps of causing the device to determine the pacing stimulus magnitude, based, at least in part, upon an analysis of the physical parameters of the patient. (Dependent claims 8, 9, 10 and 16 have been amended to place them in a form consistent with amended claim 1). Independent claims 24 and 30 have been amended to require a controller configured to determine a magnitude of pacing stimuli based at least in part on an analysis of a patient physical parameter performed by the controller. Independent claim 31 has been amended to require automatically determining in a processor a magnitude at which to supply pacing stimuli based, at least in part, on a determination by the processor of whether a defibrillation shock had previously been provided to the patient.

These requirements are not found in Kramer. They clearly distinguish over Kramer's teaching of a determination of pacing stimulus magnitude based on user input. Kramer does not teach a device that determines pacing stimuli magnitude based on an analysis of sensed patient physical parameters or based on whether the device previously supplied a defibrillation pulse to the patient.

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The Examiner has pointed to a passage at col. 14, lines 13-23 of Kramer that mentions "predetermined selectable quantities" and "instructions from the CPU." However, this passage does not teach an automatic determination of magnitude of pacing stimuli based on analysis of a physical parameter, or a controller configured to do this. Kramer instead teaching that the magnitude of pacing pulses is determined by an operator who inputs his/her choice either through the dial 245 of Fig. 17 or through the data input terminal 238 of Fig. 15.

At Para. 25 of the Detailed Action, the Examiner refers to the passage at col. 14, lines 35-39 which states: "... The human operator would merely push button 256 on the console to deliver an electrical shock..." [emphasis added]. This sentence clearly refers to delivery of a single shock. This describes defibrillation therapy, not pacing. Pacing therapy is not "an electrical shock" but instead is a series of electrical pulses delivered at a pacing rate.

The cited passage in Kramer does not teach a device making a determination of pacing stimulus magnitude based on analysis of physical parameters. This is even more evident when one looks at the cited passage in light of col. 12, lines 40-45 of Kramer, which discusses how the expert system functions in the context of pacing therapy, saying:

The algorithm of the expert system for the treatment of bradycardia is illustrated in FIG. 18F. As shown in block 800, this algorithm utilizes heart rate. In response to the prompts shown in block 810, it is the intent of the present invention that the operator would input data into the CPU using data input terminal 238 of FIG. 15. The expert system would then use this data to proceed with the algorithm, as shown in blocks 820-850. [emphasis added]

The Examiner's interpretation of col. 14, lines 35-39 as a teaching about pacing contradicts the above-quoted passage; it requires a reading of Kramer that makes the Kramer reference internally inconsistent. This is not a well-founded basis for an anticipation rejection.

With respect to the Examiner's remarks on claim 7 at paragraphs 7 and 26 of the Detailed Action, claim 7 requires that the step of obtaining and analyzing physical Filed: 11/13/2003

parameters to determine whether the patient has a heart condition for which an appropriate treatment is defibrillation or pacing, includes determining whether a defibrillation shock has been delivered to the patient within a predetermined period of time. Accepting (for the sake of argument) the Examiner's position that Kramer teaches determining whether a defibrillation shock was delivered within a predetermined time, Kramer's determination of shock delivery is done merely to inform the user. It is in no way used to determine whether a patient's heart condition is treatable through defibrillation or pacing, as required by claim 7.

With respect to the Examiner's remarks on claim 8 at paragraphs 7 and 26 of the Detailed Action, claim 8 requires the step of obtaining and analyzing updated physical parameters to determine whether the patient has a heart condition for which an appropriate treatment is either a defibrillation shock or pacing stimulus. Even if Kramer teaches an obtaining and analyzing of updated parameters, the updated parameters are in no way used to determine a patient heart condition that is appropriately treatable through defibrillation or pacing, as required by claim 8.

With respect to the Examiner's remarks on claims 15-19 and 21, Applicant had, in the Response field on October 8, 2007, taken issue with the Examiner's assertion that "CPR includes oxygen therapy", and had submitted evidence that it is well known that oxygen therapy is delivered with oxygen therapy equipment and therefore a teaching of CPR alone is not a teaching of oxygen therapy. The Examiner has not presented any evidence to refute this. A mere assertion of belief that rescue breathing is oxygen therapy is not sufficient to refute the evidence placed in the record by Applicant.

Additionally, the Examiner's assertion that rescue breathing constitutes oxygen therapy because of the exchange of gases between rescuer and patient necessitates the conclusion that the simple act of breathing is self-administered oxygen therapy, since one is inhaling gases that include oxygen. This shows that the Examiner's position is simply not reasonable.

The Examiner has also asserted that administration of chest compressions is oxygen therapy because chest compressions will force oxygenated blood to circulate through a patient's body. This position, that something which forces oxygenated blood to circulate is "oxygen therapy", is unreasonable on its face. This interpretation of the term "oxygen therapy" would include drugs that affect heartbeat and even aerobic exercise. This is an unreasonable interpretation of the term "oxygen therapy" under any circumstances, let alone where Applicant has placed evidence in the record to address the commonly understood meaning of the phrase "oxygen therapy".

In view of the Examiner's failure to refute the evidence previously submitted by Applicant, Applicant maintains the traversal of the Examiner's takings of official notice of the meaning of "oxygen therapy".

For at least the reasons discussed above, claims 1-3, 7-8, 15-19, 21, 24, and 27-31 are not anticipated by Kramer.

## § 103 Rejections of the Claims

Claim 6 has been rejected under 35 U.S.C. § 103 as unpatentable over Kramer in view of Kroll, U.S. Patent No. 6,167,306. The above arguments concerning Kramer are applicable here as well. Kroll does not have any teachings which makes up for what is lacking in Kramer. Kroll does not include any teaching of determining a magnitude for pacing stimuli. For at least these reasons, claim 6 is patentable over Kramer in view of Kroll.

Claims 4-5, 8-17, 20, 23, and 25-26 have been rejected under 35 U.S.C. § 103 as unpatentable over Kramer in view of Snyder (U.S. Patent 6,356,785). The arguments above concerning the Kramer reference are applicable here as well.

The Examiner's 103 rejections based on the Kramer-Snyder combination are based on an assertion that "Snyder et al. teach adjusting the pacing stimulus based on the updated parameters, including blood oxygen levels." Applicant again takes issue with this statement. It is an inaccurate representation of Snyder's teachings. As pointed out in the October 8, 2007 response, Snyder's only teaching relating to

transcutaneous pacing is the provision of a prompt to a user to consider pacing. Figures 15, 16B and 17B simply do not set forth a teaching of adjusting the pacing stimulus based on any updated parameters.

In response to the Examiner's remarks on claims 8-9, 20 and 25, Snyder does not teach any adjustment of pacing stimuli based on updated physical parameters, including blood oxygen levels. Claim 9 as amended requires causing the device to adjust the magnitude and pacing rate based in part on updated parameters. Kramer does not teach any determination of pacing stimulus parameters by a device based on physical parameters. Snyder does not teach any determination or adjustment of pacing stimulus magnitude or rate. Combining these two references cannot, therefore, result in the claimed subject matter.

In the Response to Arguments, the Examiner has cited Col. 25, line 26-30 of Snyder, saying that this passage is "where Snyder explicitly teaches the motivation for changing and adjusting the pacing stimuli set forth in Kramer based on an updated status of the patients condition." This is a misrepresentation of the cited passage. This passage teaches a change from one treatment protocol to another based on a changed diagnosis. There is no explicit (or implicit) teaching of a motivation for changing and adjusting pacing stimuli parameters.

In claim 26, the controller is configured to terminate the discharge of the energy device. Neither Snyder nor Kramer teaches automatically terminating pacing therapy or a device with a controller that will terminate pacing therapy based on an updated patient parameter. Col. 17, lines 10-18 of Snyder teaches a pause in prompting and does not include any teaching related to a change in pacing therapy.

Snyder does not explicitly teach terminating a therapy based on updated physical parameters. Snyder only teaches providing a particular prompt to a user if normal cardiac function is detected.

For at least the reasons discussed above, claims 4-5, 8-17, 20, 23, and 25-26 are patentable over Kramer in view of Snyder.

AMENDMENT in response to Office Action of December 28, 2007

Application no. 10/713,177

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Claim 22 has been rejected under 35 U.S.C. § 103 as unpatentable over Kramer in view of Snyder and further in view of Sherman, U.S. Patent Application Publication No. 2001/0018562.

The arguments made above concerning Kramer and Snyder are applicable here as well. Sherman does not contain any teaching that makes up for what is lacking in Kramer and Snyder. Sherman does not teach any determination of a magnitude of a pacing stimulus, as required by claim 22. For at least this reason, claim 22 is patentable over Kramer in view of Snyder and further in view of Sherman.

For at least the reasons discussed above, the Examiner has failed to establish anticipation or prima facie obviousness of the claimed subject matter.

### **CONCLUSION**

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Applicant believes that no additional fees are needed for processing of this Amendment. However, if any fees are due, please charge any such fees or credit any overpayment to deposit account number 13-2546. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Respectfully submitted,

Date: <u>April 28, 2008</u>

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